QUALITY MANAGEMENT PLAN (QMP)

for the

ETV Safe Buildings Monitoring and Detection Technology Verification Program
Version 1

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1.0 GENERAL PROVISIONS

1.1 INTRODUCTION

This document, "Quality Management Plan (QMP) for the ETV Safe Buildings Monitoring and Detection Technology Verification Program" describes the quality system that will be employed by Battelle in operating this program. This system is designed to be consistent with ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs", the U.S. Environmental Protection Agency (EPA) document "Environmental Technology Verification Program *Quality Management Plan*", Version 2.0, dated December 2002, *EPA Requirements for Quality Management Plans* (QA/R-2, dated March 2001), and the Information Quality Guidelines (http://www.epa.gov/oei/qualityguidelines/) published by EPA's Office of Environmental Information.

1.2 PURPOSE

1.2.1 The purpose of this program is to conduct testing to verify the performance of commercially-available technologies for detecting and measuring toxic industrial chemicals (TICs) and chemical and biological warfare agents on surfaces and in air. The verification testing activities of this program encompass the full range of monitoring and detection technologies, and as part of the larger Environmental Technology Verification (ETV) program are focused on providing technology users with objective, high-quality performance data for detection and monitoring systems that will support technology selection decisions.

1.3 SCOPE AND FIELD OF APPLICATION

1.3.1 This document encompasses activities that Battelle as an EPA verification organization (VO), shall utilize to assure the quality of products and services provided for this program.

1.3.2 This QMP applies to personnel involved in and activities conducted for the ETV Safe Buildings Monitoring and Detection Technology Verification (SBM&DTV) program and contains the minimum specifications and guidelines that are applicable to the program's quality management functions and activities based upon ANSI/ASQC E4-1994. These include, but are not limited to, personnel qualification and training, procurement of items and services, documents and records, computer hardware and software, planning, implementation for work processes, assessment and response, and quality improvement provisions.

1.4 BACKGROUND

1.4.1 Battelle's organization includes four Business Divisions. The SBM&DTV Program will be managed within Battelle's Energy/Environment Business Division. The Energy/Environment Business Division includes approximately 500 chemists, engineers, statisticians, and support personnel. Staff and facilities will be drawn from the Energy/Environment Business Division and other Battelle divisions to support the program. Staff expected to be involved in the program include those with expertise in

chemical and/or biological detection and monitoring systems, stakeholder involvement, and program promotion and communication. Key Battelle facilities that are available for the program's use include comprehensive laboratory analysis equipment; field sampling and analysis equipment; certified chemical surety and biological containment facilities; environmental chambers; and real-world test sites.

The organization chart for this program is provided in Figure 1-1 and shows key program staff and their reporting lines. For this program the key program staff are:

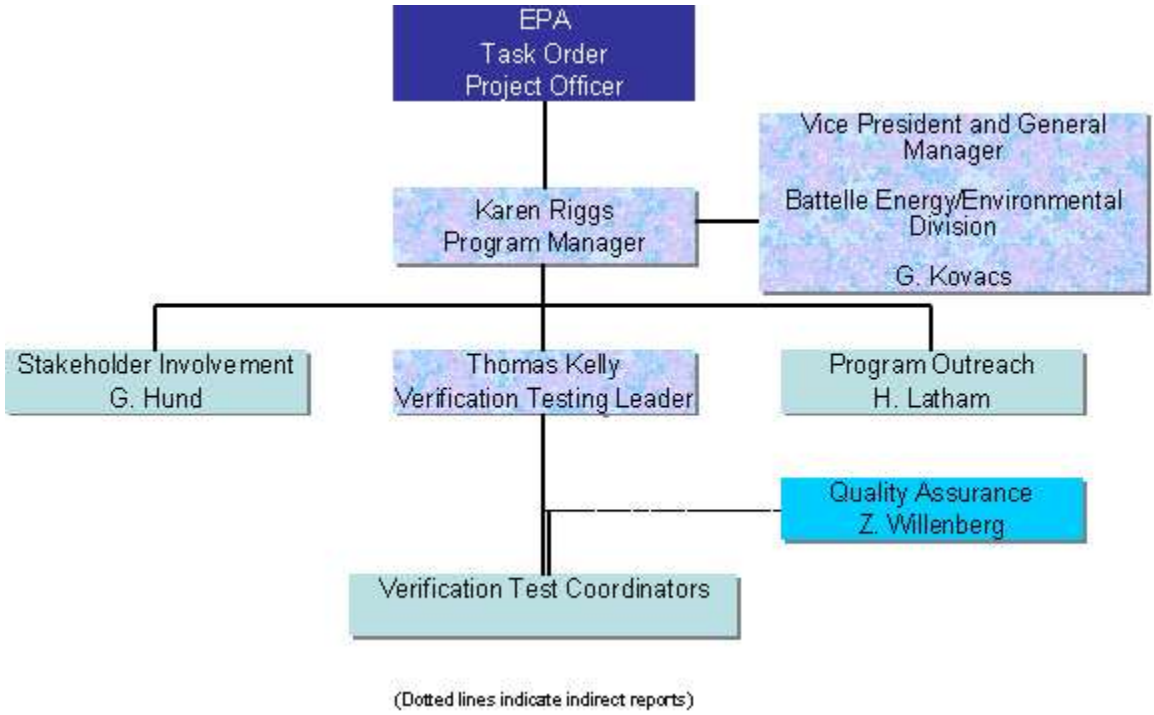

Figure 1-1. Organization for Safe Buildings Monitoring and Detection Technology Verification Program

ETV Program Manager: Ms. Karen Riggs is Battelle's ETV SBM&DTV Program Manager with responsibility for meeting overall contractual requirements (technical, budget, schedule) for this work. Ms. Riggs reports directly to Dr. Gregory Mack, a Vice President in the Energy/Environment Business Division. Dr. Mack will provide Ms. Riggs and the other key program staff with direct support in securing and deploying Battelle resources for the program. Mr. Kovacs, manager of Battelle's Energy/Environment Business Division, will have ultimate responsibility for ensuring that necessary Battelle facility and staff resources are available to support the program. Ms. Riggs will serve as the point of contact for EPA's Task Order Project Officer (TOPO) on issues related to the Blanket Purchase Agreement between Battelle and EPA under which program activity is performed.

Verification Testing Leader: Dr. Tom Kelly is the Verification Testing Leader and has responsibility for the scientific and technical aspects of verification testing. Dr. Kelly directs the activities of verification test coordinators in developing relationships with

vendors, developing test/QA plans, planning verification tests, and preparation of Verification Reports and Verification Statements. Dr. Kelly is a Senior Research Scientist in Battelle's Energy /Environment Division reporting to Dr. Gregory Mack. As the SBM&DTV Verification Testing Leader, Dr. Kelly will report to the ETV SBM&DTV Program Manager, Ms. Riggs.

Quality Assurance Manager: Mr. Zachary Willenberg is the Quality Assurance Manager for this program. He is the Quality Assurance auditor for Battelle's Measurement and Data Analysis Systems Product Line and in his capacity as the program's Quality Assurance Manager he will report to Mr. Gabor Kovacs, Vice President and General Manager of Battelle's Energy/Environment Business Division.

Stakeholder Involvement Leader: Ms. Gretchen Hund is the Stakeholder Involvement Leader for the program with primary responsibility for stakeholder involvement. Ms. Hund will report directly to Ms. Riggs. Ms. Hund is a Staff Scientist at Battelle.

Program Outreach Leader: Ms. Helen Latham is the Outreach Leader for this program. In that capacity, she prepares press releases and newsletters, coordinates presentations at technical conferences, and organizes Technology Field Days and other events. She will report directly to Ms. Riggs in support of this program.

Names, mailing/email addresses, and phone/facsimile numbers of these key ETV SBM&DTV Program staff are included in Appendix I.

1.5 DEFINITIONS

1.5.1 Verbs for clarity:

Shall, must: when the element is required and deviation from the specification will constitute nonconformance with this QMP

Should, will: when the element is recommended

May: when the element is optional.

1.5.2 **Program Quality Management Plan (QMP)** – Procedures for quality-related activities developed and implemented by Battelle to assure quality in the work processes and services developed for this program.

Stakeholders – Representatives of verification customer groups including buyers and users of technology, consulting engineers, representatives of finance and export communities, and government permitters and regulators. Stakeholders are selected based upon their expertise and interest in chemical and biological detection and monitoring and their availability and willingness to provide input for this program.

Test/Quality Assurance (QA) Plan – The plan developed by Battelle, with appropriate input, for verification testing of a specific type of monitoring technology. The test/QA plan provides the experimental approach with clearly stated test objectives and associated

quality objectives for the related measurements and may incorporate or reference standard operating procedures (SOPs).

Vendor – An individual, company, or organization which has the authority to submit a technology for verification testing.

Verification Organization – A public or private sector organization selected by EPA to implement the ETV program by conducting verification testing to provide unbiased and objective test performance data on monitoring or detection technologies.

Verification Organization Program Manager – The person designated by the verification organization with the responsibility to manage the program and serve as the chief point of contact with the EPA TOPO.

Verification Organization Quality Assurance Manager – The person designated by the verification organization with the responsibility to manage quality assurance for the program on behalf of the verification organization Program Manager.

Verification Report – A complete detailed summary of procedures and results for a single verification test on a single technology.

Verification Statement – A summary statement approved by EPA that reports quantitatively but without endorsement, the performance of a tested technology in a verification test. Appendix II presents an example verification statement.

2.0 MANAGEMENT SYSTEMS

Battelle's quality policy is to provide services, products, and data of the highest quality that meets or exceeds our client's requirements and expectations. To this end, quality programs such as this QMP, and quality achievement, shall be fully supported by Battelle management and staff.

2.1 MANAGEMENT AND ORGANIZATION

2.1.1 Battelle management is responsible for committing to a quality policy and for creating work environments in which all personnel strive for the highest quality of services and products. Management shall also provide the Program Manager the authority to ensure the following:

- That all applicable elements of the quality system as described in this QMP are understood and are implemented in the program;
- That adequate personnel and resources are available to plan, implement, assess, and improve services and products relevant to the program;
- That staff is (are) clearly designated to stop unsafe work and work of inadequate quality as affects the program.

2.2 QUALITY SYSTEM AND DESCRIPTION

2.2.1 The Battelle quality system to be implemented for this program according to this QMP is intended to conform with the specifications listed in:

- ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs";
- EPA document "Environmental Technology Verification Program *Quality Management Plan*", Version 2.0, December 2002;
- EPA document "EPA QA/R-2, *EPA Requirements for Quality Management Plans*, March 2001.

2.2.2 The principal quality system document governing general and specific responsibilities for program management and staff, responsibility and authority for all technical activities, and reporting lines is this document, the " Quality Management Plan for the ETV Safe Buildings Monitoring and Detection Technology Verification Program".

Individual verification tests will conform both to this QMP and the applicable test/QA plan document(s) and applicable SOPs.

This QMP and any revisions will be controlled documents identified by a unique Battelle document number (QMP Section 2.5.1) and will be distributed according to a published list maintained by the Quality Assurance Manager.

The QMP review will be documented by the Quality Assurance Manager and Program Manager by signing and dating the copy of the QMP routed for review. Any revisions to the QMP will be compiled by the Quality Assurance Manager for review, approval, and

distribution. The approved QMP has a scheduled review interval of one (1) year.

The initial approved QMP will serve as Version 1, which will be designated, with its effective date, in the upper right corner of each document page. Revisions will be so designated beginning with '2' and will subsequently be numbered and dated as applicable. Battelle staff to whom controlled copies are issued will be responsible for disposal of outdated QMP versions.

2.2.3 The scope of the program quality system applies to all Battelle personnel providing products and services for the program. All key staff working in the program shall be knowledgeable regarding the QMP requirements.

2.2.4 Quality procedures documentation includes maintenance of all inspection and review/ assessment records, listing of all controlled documents (QMP Section 2.5.1), and retention of records pertaining to personnel training and qualification, instrument maintenance and calibration, and test methods/operating procedures.

2.2.5 Program-specific quality controls are initiated upon approval of this QMP prior to implementing any verification testing activities. Planning actions documented through approved test/QA plans shall also serve as quality control mechanisms for verification testing.

In-process quality controls, through conduct of inspections followed by assessment reports and verification of corrective actions when required, shall also be performed and recorded.

Implementation of a complete and consistent assessment of technical operations provides overall control of program activities. This will be accomplished by the Quality Assurance Manager according to Section 3.0 in this QMP.

2.2.6 An external quality systems audit (QSA) of the Battelle quality system will be performed in the first year after the QMP is approved by the EPA TOPO. In addition, an independent technical systems audit (TSA) will be performed by the EPA Quality Manager or designee, at least once per year during program operation.

2.3 PERSONNEL RESPONSIBILITIES, QUALIFICATIONS, AND TRAINING

2.3.1 Responsibilities

2.3.1.1 Verification Organization Responsibilities. In accordance with EPA's ETV QMP dated December 2002, Battelle's Verification Organization responsibilities for the program include the following:

- Establish, attend, and/or conduct meetings of stakeholder committees with representation from major customer groups;
- Maintain communication with EPA to assure mutual understanding and conformance with EPA quality procedures and expectations and ETV policies and procedures;
- conduct outreach activities to publicize the progress and results of

technology verifications within this program;
- Develop, review, revise, and/or oversee test/QA plans in cooperation with technology vendors and stakeholders;
- Solicit technology vendor proposals or vendor products;
- Manage the oversight and conduct of verification activities;
- Assure that quality procedures are incorporated into all aspects of the program;
- Perform ETV activities within the documented quality system;
- Prepare ETV verification reports and statements at the completion of each technology verification;
- Appoint a quality manager, responsible for ensuring that the program's quality systems are in compliance with E-4 and EPA ETV QMP, and that the program's operations comply with this QMP.

2.3.1.2 Key Staff Responsibilities. Battelle is committed to operate an effective quality system that ensures compliance with all ETV Program requirements. The responsibilities of Battelle key staff who will be performing verification testing activities addressed by this Quality Management Plan are listed in Table 2-1.

Table 2-1. Personnel Responsibilities for the Program

Program Team Member	Responsibilities
Program Manager Karen Riggs	• Ultimate responsibility for all aspects of the SBM&DTV Program
	• Maintain contact with EPA TOPO on on-going basis
	• Manage oversight and conduct of verification activities
	• Assure that quality procedures are incorporated and implemented
	• Review/approve test/QA plans
	• Operate program activities within the documented quality system
	• Review and approve verification reports and verification statements
Verification Testing Leader Thomas Kelly	• Coordinate planning, performance, and data reviews of technology verification testing consistent with the program QMP requirements
	• Coordinate review of applications from technology vendors wanting to have their technology verified
	• Work with stakeholders and EPA to identify and prioritize technologies for verification
	• Review verification reports and verification statements
	• Oversee/assist in problem resolution involving verification tests
Quality Assurance Manager Zachary Willenberg	• Ensure that the quality system is compliant with EPA-specified standards.
	• Advise the Program Manager of any QA/QC problems and oversee corrective actions.
	• Ensure that the QMP includes sufficient and appropriate specifications for QA/QC as required for the program.
	• Interact with program management and technical personnel to ensure that QA/QC procedures are understood.
	• Ensure that the program QMP, the EPA/ETV QMP, and the ANSI/ASQC E4 document are followed for performing system audits.
	• Perform Technical System Audits (TSA) for each verification test and perform Audits of Data Quality (ADQ) on at least 10% of all generated data.

Program Team Member	Responsibilities
	• Ensure that assessment reports are prepared and distributed that detail appropriate corrective action and that implementation will be responded to by personnel and returned to the Quality Assurance Manager. Problems that are not addressed will be brought to the attention of management.
	• Review test/QA plans, SOPs, and verification reports and statements.
	• Review all quality system documentation, including this document, at intervals necessary to ensure their integrity. Such reviews will be recorded and documents will be revised if necessary. All previous original (i.e., signed) revisions will be retired and archived.
	• Act as a QA resource to respond to quality needs and problems. Answer questions and train laboratory staff in QA/QC requirements and procedures.
	• Manage QA Coordinators in specific Battelle laboratories performing verification testing to ensure overall compliance with program QMP
Verification Test Coordinators	• Schedule verification tests
	• Solicit technology vendors
	• Select/assemble Verification Team to perform specific technology verification test/data reviews
	• Oversee development and implementation of test/QA plans
	• Verify 100% of data at the time it is collected and evaluate results of quality control analyses to determine if quality goals and objectives have been met
	• Inform the Verification Testing Leader of potential quality control problems
	• Perform corrective action at the direction of Program Manager and Quality Assurance Manager
	• Document results of quality control analyses and include them with sample results and historical data files
	• Maintain instrumentation in accordance with the QMP, test/QA plan, SOPs, and the manufacturer's instructions
	• Prepare verification reports and verification statements
	• Prepare and implement test/QA plans
Stakeholder Involvement Leader Gretchen Hund	• Facilitate stakeholder meetins
	• Conduct and oversee activities to establish and maintain an active stakeholders committee
	• Prepare and coordinate review of stakeholder committee meeting minutes
	• Identify and secure the commitment of new stakeholders as needed
Program Outreach Leader Helen Latham	• Prepare and distribute newsletter on program activities
	• Maintain and continue to expand mailing list for program communications
	• Identify appropriate conferences and workshops to disseminate program information
	• Provide program information for outreach needs requested by EPA/ETV Program Office

2.3.1.3 Stakeholders' Responsibilities. The responsibilities of the stakeholders for the program include the following:

- Assist in prioritizing the types of technologies to be verified;
- Review program-specific procedures and documents including test/QA plans, verification reports, and verification statements;

- Assist in the definition and conduct of outreach activities appropriate to the technology area and customer groups;
- Serve as information conduits to the particular constituencies that each member represents.

2.3.2 Qualification and Training

Battelle personnel qualification and training shall target technical work performed directly in support of detection and monitoring technology verification testing activities. These qualifications and training may include:

- Formal education in physical and/or biological sciences (i.e., chemistry, physics, engineering, molecular biology, toxicology, biochemistry);
- Experience in chemical and biological (CB) agent sampling and analysis;
- Training on standard analytical instrumentation such as gas chromatographs, mass spectrometers, Fourier transform infrared spectrometers, etc.;
- Experience in designing experiments to verify the performance of monitoring and detection technologies.

Battelle personnel working on program activities shall have, at a minimum, documentation, maintained by Battelle permanently, for each of the following:

- Education history which can include formal qualification or certification relevant to technical, quality assurance, or management disciplines;
- Work experience as academic or on-the-job performance in technical and/or management areas;
- Experience in the application of quality assurance/quality control requirements in technical performance or data verification.

2.3.2.1 Formal qualifications and certifications in the form of actual or verified-copy documentation for specific disciplines shall be maintained in the staff member's qualification/training file.

2.3.2.2 Technical management and training received in-house or offsite shall be recorded and forms, memos, or certificates retained. Performance on either task, project, or program assignments is to be considered as part of training.

2.3.2.3 Retraining needs based on job requirements shall be determined by the staff member and respective management. To maintain staff proficiency, opportunities provided by Battelle or other sources shall be made available, preferably on an annual basis.

2.3.2.4 Personnel job proficiency based on witnessed performance on-the-job by a qualified trainer/staff member designee shall be documented. Specific method requirements for instrument inspection, performance, and maintenance are objective measures that could be considered. Specific performance based on national certification requirements can be recorded with certificates or other documentation. Basic areas of proficiency for verification testing may include,

at a minimum:

- Sample management practices, such as chain of custody records;
- Sample handling and storage and use of standards and reagents;
- Instrument inspection, use, and maintenance;
- Data acquisition, analysis, and verification.

2.3.2.5 Training resources should be offered on-site by Battelle for facility requirements, such as general computer software use (E-mail, spreadsheets) or program management. Off-site training and technical society membership should be available for specific disciplines contributing to the staff member's overall job proficiency.

2.3.2.6 Participants working on behalf of Battelle in support of the program and/or individual test operations are expected to provide the Verification Testing Leader, or designee, with:

- Educational background and/or degree(s) relevant to technical areas represented in this program;
- Work experience related to the monitoring and detection technology category undergoing verification;
- Experience in quality management.

2.4 PROCUREMENT AND ACCEPTANCE OF ITEMS AND SERVICES

2.4.1 Policy

Procurement technical and quality requirements are generally based upon value (cost, durability, maintainability), performance (specification compliance, operating conditions, calibration capacity), delivery (timeliness, ease of ordering), customer support (responsiveness, technical ability); and completeness and coherence of instructions (clarity, accuracy).

2.4.2 Procurement

Staff members must follow Battelle Procurement System Procedures (PSPs). Technical and quality requirements for items and services procured for a specific verification test shall be included in the test/QA plan. These requirements will typically be specified under materials and/or measurement system equipment. The request for items or services will initiate from the Verification Testing Leader or technical staff with approval for purchase from the Program Manager or designee. All procurement documentation is reviewed and approved by the Program Manager or designee to ensure completeness and accuracy before these requests are forwarded to the Procurement Office for processing.

2.4.3 Acceptance

2.4.3.1 Testing equipment procured for activities affecting quality shall be calibrated to ensure accuracy with required specifications listed in the test/QA plan. Any

discrepancies shall result in the return of the item to the supplier. Verification, storage, and maintenance records will be included in individual verification test records.

2.4.3.2 Testing materials procured for activities affecting quality (e.g., reference standards or gases) shall be accompanied with a Certificate of Analysis (COA). The COA will be examined to ensure that the listed specifications are within the required limits. The COA will be retained and included in the verification test records.

2.5 DOCUMENTS AND RECORDS

2.5.1 Controlled Documents

Document control is the system which ensures that only the latest revision of the defined documents are used by Battelle staff participating in the SMB&ETV Program. The system includes retention of the document with original signed page(s) in a limited access storage area, a unique numbering system for all documents (typically identified by revision number and/or date), and an issue list for each document. Such documents are defined as "controlled documents" and can be revised only by the personnel listed within each document or this QMP. The following is a list of the controlled documents within this QMP:

- Quality Management Plan for the ETV Safe Buildings Monitoring and Detection Technology Verification Program;
- Standard Operating Procedures;
- Test/QA Plans.

Controlled document identification will consist of a number, date, and version, if applicable, assigned to the document by the Quality Assurance Manager or designee. A current Master List of Controlled Documents and Distribution shall be maintained by the Quality Assurance Manager.

As a controlled document, approved copies of the QMP will be maintained and issued to program staff by the Quality Assurance Manager or designee. Obsolete or superseded documents shall be removed from operations when new documents are provided. Notification will accompany new document versions that the previous version is to be removed from use and destroyed. Staff members are responsible for destroying outdated versions of documents assigned to their person. The Quality Assurance Manager is authorized to remove outdated documents observed during inspections and reviews. All controlled documents, including historical revisions, will be retained at least seven years after final payment of the blanket purchase agreement, with the exception of the SOPss which will be permanently archived.

2.5.2 Test Records

2.5.2.1 Active Test Records. All test records shall carry minimum identification pertaining to title, responsible person or author, and date. All manual entries

shall be entered using ink and shall be initialed and dated by the individual recording the entry. Changes to entries, manual or electronic, shall not obscure the original record during the correction process, and shall be initialed and dated by the individual recording the correction. A short explanation will be added to non-obvious corrections.

2.5.2.2 Storage of Test Records. Verification test records specific to the program shall be retained for at least seven years after final payment under the blanket purchase agreement. All program records needed to both reconstruct test activities and verify that reported data were collected in a quality manner reconciled to this QMP and program requirements will be maintained in an appropriate area of limited access until either transferred to EPA ORD Records Management or properly destroyed with EPA permission. The Quality Assurance Manager will retain, as permanent record, documentation of the transfer or destruction of program records.

2.5.3 ETV Program Records

The following program records will be retained, as per ETV directives, for at least seven years after final payment under the blanket purchase agreement.

- Minutes of stakeholder meetings;
- Blanket purchase agreement records;
- Verification Reports;
- Verification Statements;
- Battelle Assessment reports (Section 3.3.4).

2.5.4 Document and Record Preparation, Review, Approval, and Distribution

Document and record review and approval shall be performed as provided in Table 2-2 and are detailed below.

2.5.4.1 Preparation. Individual case requirements and this QMP shall guide document and record content and/or format. For this program, guidance for content and/or format are derived by EPA/ETV directive and the following documents:

- EPA document "Environmental Technology Verification Program Quality Management Plan", December 2002, or most current version;
- ETV Program Web Page (specific content and format for verification statements);
- ANSI/ASQC E4-1994. *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*;
- EPA QA/R-5. *EPA Requirements for Quality Assurance Project Plans;*
- EPA QA/G-4. *EPA Guidance for Data Quality Objective Process*;
- EPA QA/G-5. *EPA Guidance for Quality Assurance Project Plans*;
- EPA QA/G-6. *EPA Guidance for the Preparing Standard Operating Procedures (SOPs)*;
- EPA QA/G-7. *EPA Guidance on Technical Audits and Related Assessments*

for Environmental Data Operations;
- EPA QA/G-9. *EPA Guidance for Data Quality Assessment.*

2.5.4.2 Review/Approval. Record review/approval shall be performed by qualified technical and/or management personnel and the Quality Assurance Manager, as appropriate. The individual reviewer shall have access to all needed references.

All prepared documents in QMP Sections 2.5.1 through 2.5.3 shall require at least one review by a technical reviewer and the Quality Assurance Manager and/or Program Manager, as appropriate, prior to external distribution by Battelle. Document and record reviews are performed at the request of the Program Manager, Quality Assurance Manager, Verification Testing Leader, or other personnel.

In addition, ETV record review assigned to Battelle extends to the following documents, at a minimum, according to the ETV QMP of December 2002:

- EPA/ETV strategy;
- EPA/ETV QMP;
- Annual ETV Program progress reports.

2.5.4.3 Distribution. Once records have been reviewed and approved as required, distribution will be made as listed in Table 2-2 which is based upon the ETV QMP of December 2002. Program documents specifically requiring EPA approval before release include:

- Program QMP;
- Test/QA plans;
- ETV verification reports;
- ETV verification statements.

Table 2-2. Records Management Responsibilities for the Program

Record Type	Preparation/Updating	Review	Approval	Finals Distributed to:
ETV Verification Strategy	N/A	Program Manager	N/A	N/A
ETV Quality Management	N/A	Program Manager	N/A	N/A
CA/IAG/Contract Records	Program Manager	EPA ETV Director	N/A	N/A
SBM&DTV Program Quality Management Plan	Quality Assurance Manager	EPA Program Quality Manager	EPA Program Manager (TOPO) EPA Program Quality Manager Program Manager	Testing Staff ETV Webmaster EPA Program Quality Manager EPA Program Manager (TOPO)
Minutes of Stakeholder Meetings	Stakeholder Involvement Leader	EPA Program Manager (TOPO) Stakeholders	N/A	Stakeholders ETV Webmaster EPA Program Manager (TOPO)
Generic Verification Protocols	Verification Test Coordinators	EPA Program Quality Manager Program Manager Quality Assurance Manager Stakeholders ETV Program Director	EPA Program Manager (TOPO)	ETV Webmaster (draft and final versions) EPA Program Manager (TOPO)
Test/QA Plan (including SOPs)	Verification Test Coordinators	EPA Program Quality Manager EPA Program Manager (TOPO) Assigned Stakeholders/Peer Reviewers Program Manager Quality Assurance Manager	Vendors EPA Program Manager (TOPO)	ETV Webmaster Testing Staff Vendors EPA Program Manager (TOPO) EPA Program Quality Manager Stakeholders
Raw data	Technical Staff	Verification Test Coordinators	N/A	EPA can request copies
ETV Verification Report	Verification Test Coordinators	EPA Quality Manager Vendor Program Manager Verification Testing Leader Quality Assurance Manager Peer Reviewers	EPA Program Manager (TOPO)	EPA ETV Director EPA Program Manager (TOPO) Vendor
ETV Verification Statement	Verification Test Coordinators	EPA Program Manager (TOPO) EPA Program Quality Manager Vendor EPA ETV Director Program Manager Verification Testing Leader Quality Assurance Manager Peer Reviewers	EPA Laboratory Director	ETV Webmaster EPA Program Manager (TOPO) Vendor ETV Program Director
Annual ETV Progress Report	N/A	Program Manager	N/A	EPA Laboratory Directors
EPA Program Reviews/Audit Reports	N/A	N/A	N/A	EPA Laboratory Directors Program Manager Quality Assurance Manager
Battelle Reviews/Audit Reports	Quality Assurance Manager	Program Manager Verification Testing Leader	N/A	EPA Program Manager (TOPO) EPA Program Quality Manager
Program Monthly Reports	Verification Testing Leader	Program Manager	Program Manager	EPA Program Manager (TOPO)

NA = Indicates Battelle does not have responsibility for preparing/updating record; conducting or obtaining review; providing or obtaining approval; or distributing and/or receiving final record.

2.6 COMPUTER HARDWARE AND SOFTWARE

This QMP requires that Battelle staff understand the necessity for all computer hardware and software specifications. Staff shall utilize computer hardware and software within the acceptance criteria specified, and assures that hardware and software are installed, maintained, and used according to specifications. Any time a change in hardware components or configuration or a software modification is needed, retesting and recalibration must be performed and documentation included with facility records.

2.6.1 Hardware

All computer hardware at Battelle contains Intel based Pentium processing running a Microsoft operating system. Each personal computer (PC) primarily consists of a standard complement of Microsoft software (e.g., Word, Excel, Access, PowerPoint, and Outlook) with capabilities of running other commercial software (e.g., WordPerfect, Quattro, Lotus, SAS,) and delivery of data in any standard format. Battelle has established a contractual relationship to lease computers for Battelle staff, accompanied by a maintenance support service. Each PC is upgraded on a regular cycle (every 2 or 3 years) so that Battelle computer hardware is continually upgraded to improve performance and provide complete compatibility with current standards. Documentation of assessment and upgrades is maintained via leasing agreements established by Battelle's Information Management (IM) Department.

2.6.2 Software

Specific software required for a verification test will be identified in the test/QA plan. Most software used at Battelle is acquired commercially, loaded, and tested as specified by the publisher. Independently-developed software is not used within the program, only commercial products are used. Software used for data management activities may include Microsoft Excel or Access. Standard word processing software (e.g., WordPerfect, Word) is used to create reports.

2.6.3 Validation Policy

Since all hardware and software used in the program is commercially available, and wide public use and continued market viability is considered proof of software dependability, validation is not considered necessary. However, verification of data analysis techniques within each program (e.g., the use of formulas and macros) is required. For each defined spreadsheet a performance test document will be prepared which will contain the following:

- An overview of the application. The overview will describe what the application is required to do and specify the methods used to meet the predetermined requirements;
- References to the productivity software used (e.g., Excel XP, SigmaPlot V8.0, etc.), and the operating system (e.g., Windows 2000, Windows XP, etc.);
- A description of important equations used to derive data;
- A description of what test(s) were conducted to confirm the accuracy of the application.

2.7 PLANNING

This QMP addresses the purpose and scope of systematic, timely, and effective planning necessary to assure services and products of the highest quality.

2.7.1 Stakeholder committee(s) containing representatives of appropriate technology interest groups shall be jointly established by the EPA TOPO and Battelle. Individual stakeholders shall be selected for these committee(s) based on their expertise and interest in monitoring and detection technologies and their availability and willingness to participate.

A joint meeting of the EPA TOPO, Battelle, and stakeholder committee will be held at least once annually, with minutes of this meeting recorded, reviewed, and circulated to the stakeholders, and the EPA TOPO. The planned quality-related purposes of this meeting are to:

- Identify, revise, and/or clarify the technical and quality goals of the work to be accomplished;
- Translate the technical and quality goals into written specifications that will be used to produce the desired results;
- Consider any cost and schedule constraints within which test activities are required to be performed;
- Determine testing priorities and evaluate customer satisfaction;
- Review verification plans.

2.7.2 Systematic Planning of Verification Tests

An overall view of the EPA ETV verification process is shown in Figure 2-1. Battelle, in cooperation with the EPA TOPO, begins a systematic process to plan the individual verification tests. Systematic planning may be accomplished through any demonstrated technique such as the data quality objectives process (EPA QA/G-4 Guidance for the Data Quality Objectives Process). The planners perform the following actions:

- Convene stakeholder committees containing representatives of verification customer groups which advise during the planning process;
- Mediate and facilitate the identification and recommendation of prioritized monitoring and detection technologies;
- Refine the scope of respective monitoring and detection technology areas;
- Determine interest in verification from the manufacturers of commercial-ready monitoring and detection technologies within the defined scope of these areas;
- Prepare test/QA plan(s) which are developed to promote uniform testing for a given type of monitoring or detection technology;
- Solicit vendor agreements to participate in verification of their products based on the test/QA plan;

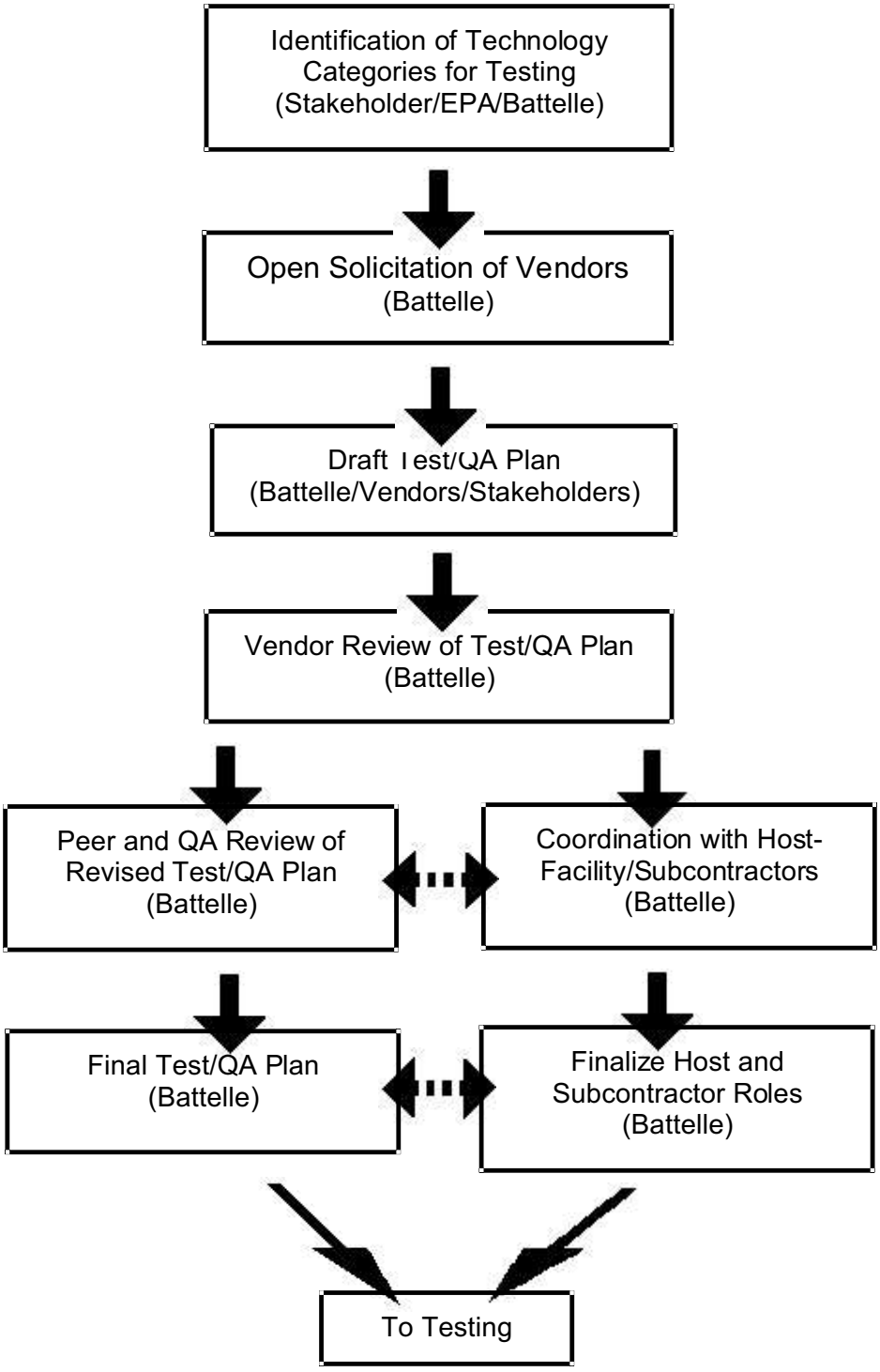

Figure 2-1. Systematic Planning of Verification Tests

- Involve host facilities, partner organizations, and any subcontracted laboratories in the planning process;
- Coordinate the review and revision of the test/QA plan(s) (by vendors, EPA, and peer reviewers) keeping in mind both the customers and EPA's objective for verification as defined in the ETV Strategy;
- Prepare final test/QA plans after testing a given type of detection or monitoring technology which includes revisions based on actual test experience.

Systematic planning process-control documents for the program include:

- The ETV Program Policy Compendium;
- The EPA ETV Program QMP;
- This QMP which defines the operational quality system necessary to provide acceptable products and services;
- Written quality procedures specific to the technology and verification test including test/QA plans and SOPs;
- Outputs from stakeholder committee meetings in the form of reviewed and distributed minutes;
- Monthly internal cost reports;
- Monthly program reports to the EPA TOPO.

2.7.3 Planning Personnel

Verification test planning shall be coordinated by Battelle among the participating organizations including EPA, the stakeholders, the vendors, and any organizations that may be providing a full-scale demonstration site. Battelle, with the concurrence and oversight of the EPA TOPO, shall identify the planning roles of the participants, and shall conduct planning activities by shared communication via teleconference, video conference, and in-person meetings, as appropriate, and within the constraints of budget.

2.7.4 Existing Data

Existing data may be used for planning, subject to the individual rules set up for each test.

2.7.5 Waste Minimization and Disposal

If waste is expected to be generated as part of a verification test, the procedures for minimization and disposal in accordance with local, state, and Federal laws will need to be included in each test/QA plan.

2.8 DESIGN OF TECHNOLOGY VERIFICATION OPERATIONS

2.8.1 Design Process

The design process produces a test/QA plan based upon the data quality objectives for the verification of the technology performance.

2.8.1.1 Design Technique. In designing verification tests, Battelle staff use consensus-accepted verification testing design including statistical methods, as appropriate. The design takes into account constraints of time, scheduling, and resources.

All relevant activities pertaining to monitoring and detection technology data collection operations shall be identified, as well as performance specifications and the appropriate controls.

2.8.1.2 Field and Laboratory Equipment and Methods. During the design process, the appropriate field and laboratory equipment which were identified during the planning for the testing of the technology verification performance, are incorporated. Appropriate test methods and operating parameters are specified.

2.8.1.3 Sampling and Analysis. If samples for analysis are taken in the field, they are handled according to procedures specified in the test/QA plan. The oversight responsibility of Battelle is to determine that the approved systems and plans contain adequate procedures for handling, storage, cleaning, packaging, shipping, and preservation of field and laboratory samples to prevent damage, loss, deterioration, artifacts, or interferences. Battelle will provide adequate chain of custody procedures, if they are required. Data retention, archival, and security is identified in Section 2.5.2.2. The following sampling and analysis design parameters should be addressed in the test/QA plan.

- Experiments to be conducted, the baseline parameters, the number of replicate tests, and the controls;
- Sampling methods, sample types, numbers, quantities, handling, packaging, shipping, and custody (if sampling is performed);
- Sample locations, storage conditions, and holding times;
- Analysis methods, quantitative measures of performance, calibration standards, calibration check standards, and performance evaluation samples, as appropriate, and as identified in the planning process;
- Methods and procedures to ensure the test produces traceable data of known and acceptable quality;
- Field and/or laboratory QA/QC activities;
- Requirements for qualifications of technical staff responsible for obtaining, analyzing, and evaluating the data;
- Procedures for the minimization and disposal of waste generated in accordance with applicable local, state, and federal laws.

2.8.1.4 Assessments. Assessments incorporated into the design include self-assessments (internal audits) by Battelle and independent assessments by the EPA. The assessments identified in the planning process are incorporated into the design. The type and minimum number of assessments are identified in Section 3.0.

2.8.2 Test/QA Plans and Standard Operating Procedures

Two types of planning documents have been identified for operation of a program in the ETV Program: test/QA plans and SOPs. The test/QA plan give the specific information needed to conduct a verification test. If another level of detail is required for describing test activities, for example operation of an instrument, an SOP will be written and attached to the test/QA plan.

2.8.2.1 Test/QA Plans. Test/QA plans are the responsibility of the Verification Test Coordinator and are reviewed by the Program Manager, Verification Testing Leader, Quality Assurance Manager, and EPA TOPO. Appropriate guidance for writing test/QA plans is available in EPA/QA G-5, *Guidance for Quality Assurance Project Plans*. Planned changes to the test/QA plan are made by written amendment. Deviations from the plan must be fully documented including date and description of deviation, and impact on the verification test. Elements of the test/QA plan include the following, and although not all elements listed are appropriate to every test, the test/QA plan will note and explain those elements that are not applicable:

- Group A: Project Management - This group of elements covers the general areas of project management, project history and objectives, and roles and responsibilities of the participants. The following nine elements ensure that the project's goals are clearly stated, that all participants understand the goals and the approach to be used, and that project planning is documented:
  - A1 Title and Approval Sheet
  - A2 Table of Contents and Document Control Format
  - A3 Distribution List
  - A4 Project/Task Organization and Schedule
  - A5 Problem Definition/Background
  - A6 Project/Task Description
  - A7 Quality Objectives and Criteria for Measurement Data
  - A8 Special Training Requirements/Certification
  - A9 Documentation and Records
- Group B: Measurement/Data Acquisition - This group of elements covers all of the aspects of measurement system design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and will be thoroughly documented:
  - B1 Sampling Process Design (Experimental Design)
  - B2 Sampling Methods Requirements
  - B3 Sample Handling and Custody Requirements
  - B4 Analytical Methods Requirements
  - B5 Quality Control Requirements
  - B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
  - B7 Instrument Calibration and Frequency
  - B8 Inspection/Acceptance Requirements for Supplies and Consumables
  - B9 Data Acquisition Requirements (Non-Direct Measurements)
  - B10 Data Management
- Group C: Assessment/Oversight - The purpose of assessment is to ensure that the test/QA plan is implemented as prescribed. This group of elements addresses the activities for assessing the effectiveness of the implementation of the project and the associated QA/QC activities:
  - C1 Assessments and Response Actions
  - C2 Reports to Management
- Group D: Data Validation and Usability - Implementation of Group D elements ensures that the individual data elements conform to the specified

criteria, thus enabling reconciliation with the project's objectives. This group of elements covers the QA activities that occur after the data collection phase of the project has been completed:

- D1 Data Review, Validation, and Verification Requirements
- D2 Validation and Verification Methods
- D3 Reconciliation with Data Quality Objectives

2.8.2.2 Standard Operating Procedures. If an SOP is attached to a test/QA plan, the following topics, from EPA QA/G-6, *Guidance for Development of Standard Operating Procedures (SOPs)*, may be included (or a reference provided):

- Title Page
- Table of Contents
- Procedures - The following are topics that may be appropriate for inclusion in technical SOPs. Not all will apply to every procedure or work process detailed.
- Scope & Applicability
- Summary of Method
- Definitions
- Health & Safety Warnings (indicating operations that could result in personal injury or loss of life)
- Cautions (indicating activities that could result in equipment damage, degradation of sample, or possible invalidation of results)
- Interferences (describing any component of the process that may interfere with the accuracy of the final product)
- Personnel Qualifications
- Equipment and Supplies
- Procedure - identifying all pertinent steps, in order, and materials needed to accomplish the procedure such as:
  - Instrument or method calibration and standardization
  - Sample Collection
  - Sample Handling and Preservation
  - Sample Preparation and Analysis
  - Troubleshooting
  - Data Acquisition, Calculations, and Reduction
  - Requirements for Computer Hardware and Software used in Data Reduction and Reporting
  - Data and Records Management
- Quality Control and Quality Assurance Section
- References

2.9 IMPLEMENTATION

2.9.1 General

Technology verification testing is performed according to the test/QA plans and technical documents (e.g., SOPs) prepared during planning. Test personnel have access to the approved planning documents, approved changes to planning documents, and all

referenced documents. When a prescribed sequence for the work is defined during the planning stages, work performed shall follow that sequence. All implementation activities are documented. Suitable documents are bound notebooks, field and laboratory data sheets, spreadsheets, computer records, and output from instruments (both electronic and hard copy). All documentation is implemented as described in the planning documents. All implementation activities are traceable to the planning documents and traceable to test personnel.

2.9.1.1 Conformance of implementation to planning is accomplished by following approved documents for the Battelle quality system implementation, verification testing, and for any field and laboratory technical operations.

Work on individual verification tests is not initiated until the approved test/QA plan is in place.

When work cannot be implemented according to the approved planning and test document, Battelle shall be responsible for providing a written amendment to the test/QA plan or deviation report for the test records. Amendments are produced for changes that are made to the test/QA plan before the proposed change is begun. Amendments must be approved internally by the Verification Testing Leader and Quality Assurance Manager. Following approval, the amendment will be distributed to all internal personnel holding a copy of the parent test/QA plan, and to the EPA TOPO. A deviation report is produced for any changes to the test/QA plan that occurred during the test. Deviation reports must be retained in the verification test records and summarized in the verification test report. Frequent deviations from established procedures should result in a retrospective review of the written document and possible revision. Amendments and deviations will include all the information displayed on the example forms shown in Appendix III.

All persons responsible for performing verification testing and those participating vendors shall receive copies of the current revision of the test/QA plan and associated documentation provided by Battelle.

Current versions of test/QA plans and any applicable methods and SOPs are required to be physically in place at each technology verification testing site.

2.9.1.2 Battelle quality assurance oversight and assessment of a verification test shall be provided by the Quality Assurance Manager or designee at intervals prescribed in each test/QA plan. This frequency, at a minimum, will be once for each verification test of a technology category. To verify full implementation of the test/QA plan, the assessment will include the testing process and any documentation associated with the process, such as sample tracking records; instrument maintenance and calibration; sample preparation and actual analysis; and data records. The Quality Assurance Manager will provide a written assessment report, verify the completion of any corrective actions needed, and retain a copy of the report with permanent Quality Assurance Manager records. The Program Manager will be included in the routing of the assessment reports

and a written copy will be provided to the EPA TOPO.

2.9.2 Implementation Procedures

2.9.2.1 Testing procedures shall be documented in approved test/QA plans and SOPs. Testing personnel, by virtue of training requirements described in this QMP, shall demonstrate proficiency of performance and knowledge of QA and program requirements for the verification test operations.

2.9.2.2 Content requirements for testing procedures may include those of existing Battelle SOPs or other referenced documents.

2.9.2.3 Following the signing of the test/QA plan and before the initiation of testing, a test kickoff meeting will be held by the assigned Verification Testing Coordinator. The Program Manager, Verification Testing Leader, Quality Assurance Manager, and all Battelle technical staff that will be utilized for the verification test will attend the kickoff meeting. Subjects to be discussed at the meeting will include, but not be limited to, a general overview of the test/QA plan, staff assignments, schedules, and assessments (QMP Section 3.0).

2.9.2.4 Review of technical program-specific procedures shall be done by personnel technically competent with respect to the procedure. Time must be allowed for the composition, review, and approval of technical procedures to be completed in advance of the actual performance.

2.9.3 Implementation Monitoring

2.9.3.1 Routine monitoring during implementation of individual verification tests will be prescribed at a minimum frequency/interval in the test/QA plan. Specifically, the test/QA plan will address a routine monitoring schedule and the required specifications of performance, or particular aspects of the process, that are determined to be critical for monitoring.

2.9.3.2 Monitoring the work process is conducted by the Quality Assurance Manager or designee and is done to:

- Ensure satisfactory performance based on requirements;
- Ensure required actions (as specified in implementation documents) are performed so that routine measurements meet specifications;
- Ensure preventive maintenance is performed and documented as specified in facility and study records;
- Ensure calibrations are performed as planned and prescribed;
- Ensure corrective actions are implemented and documented as planned in response to items of nonconformance.

3.0 ASSESSMENT AND RESPONSE

3.1 SCOPE

3.1.1 Assessments shall be planned, scheduled, conducted, and reported in order to measure the efficacy of the Battelle quality system.

3.1.2 Assessment and response elements shall include assigning appropriate, qualified persons to conduct assessments at planned, scheduled intervals (see Table 3-1); having provisions for timely responses and implementation of corrective actions if needed; and completing the evaluation process with written reports to technical and management staff.

3.1.3 Assessment types, responsibility, and schedule devised for the program (based upon Table 3-1) are defined as follows:

Quality Systems Audit – an on-site review of the implementation of the program quality system as documented in the program QMP. This review is used to verify the existence of, and evaluate the adequacy of, the internal quality system. This assessment is the responsibility of the EPA Program Quality Manager and will be performed in the first year after the QMP is approved.

Technical Systems Audit – a qualitative on-site evaluation of sampling and/or measurement systems associated with a particular verification test. The objective of the Technical Systems Audit (TSA) is to assess and document the acceptability of all facilities, maintenance, calibration procedures, reporting requirements, sampling, and analytical activities, and quality control procedures in the test. Conformance with the test/QA plan and associated methods and/or SOPs is the basis for this assessment. The Quality Assurance Manager conducts a technical systems audit at least once during each verification test. The EPA has the option to conduct an independent technical systems audit at least once a year.

Performance Evaluation Audit – a quantitative evaluation of a measurement system. The type and frequency of performance evaluation self-audits to be performed by the Verification Test Coordinator or designee (and assessment of results by the Quality Assurance Manager) are specified in the test/QA plan for each verification test. The value or composition of reference materials must be certified or verified prior to use, and the certification or verification must be adequately documented. The need for independent performance evaluation audits will be determined by the EPA TOPO.

Audits of Data Quality – an examination of the verification data after they have been collected and 100 percent verified by test personnel. The Quality Assurance Manager will audit at least 10 percent of all verification data. The need for independent audits of data quality will be determined by the EPA TOPO.

Table 3-1. Assessment for the ETV Safe Buildings Monitoring and Detection Technology Verification Program

Level	Assessment Tool	Assessors	Responders	Basis of Assessment	Minimum Frequency	Reason for Assessment	Report Reviewed By
Program	Quality Systems Audit	EPA Program Quality Manger	Battelle	Program QMP	Once; thereafter, as required	Assess Quality Management Practices of Verification Organization	EPA directors of quality assurance EPA TOPO Battelle Program Manager ETV Program Director
Program	Technical Systems Audit	Self Quality Assurance Manager Independent EPA Program Quality Manager	Battelle	Test/QA Plans	Self Once per verification test Independent Once per year, as applicable	Assess Technical Quality of Verification Tests	EPA TOPO Battelle Program Manager EPA Program Quality Manager
Program	Performance Evaluation Audits	Self Quality Assurance Manager Independent EPA Program Quality Manager	Battelle	Test/QA Plans	Self Each test, as applicable Independent for each verification, as applicable	Assess Measurement Performance	EPA TOPO Battelle Program Manager EPA Program Quality manager
Program	Audits of Data Quality	Self Quality Assurance Manager Independent EPA Program Quality Manager	Battelle	Raw Data and Summary Data	Self At least 10% of the verification data Independent for each verification, as applicable	Assess Data Calculations and Reporting	EPA TOPO Battelle Program Manager EPA Program Quality Manager

3.2 GENERAL REQUIREMENTS

3.2.1 Each assessment shall be fully documented. The Quality Assurance Manager will archive all internal assessment reports generated for the program.

Each assessment must be responded to by the appropriate level of management. The Battelle quality assessment reports shall require a written response by the person performing the inspected activity, and acknowledgment of the assessment by the Verification Testing Leader and the Program Manager.

3.2.2 Corrective actions must be documented and approved on the original assessment report, with a detailed narrative in response to the assessor's finding. Initials and date are required for each corrective action response. Acknowledgment of the response will be provided by the Verification Testing Leader and Program Manager.

3.2.3 Implementation of corrective actions must be verified by the Quality Assurance Manager or designee to ensure corrective actions are adequate and have been completed. This will be done in real-time if corrective actions can be immediately performed and signed off on the assessment report; or, should the corrective action require additional approvals not immediately available on-site, the Quality Assurance Manager or designee may need to repeat the inspection in order to corroborate the implementation and effectiveness of the corrective action.

3.3 PLANNING AND PROCEDURES

3.3.1 Assessment Planning

Assessment planning is performed by Battelle's Quality Assurance and the Program Manager prior to the actual performance of any assessments. Planning the assessment scope helps provide the type of evaluation information needed to determine whether procedural compliance and technical requirements are being met during verification testing.

Assessment planning by Battelle shall include a kickoff meeting with the verification testing team where at least the following information will be discussed:

- Assessment plan format;
- Schedule of assessment(s);
- Notification to affected parties;
- Specific assessment requirements (personnel lists, equipment lists, and availability of test/QA plans);
- Assessment checklist consistent with requirements;
- Assessment report format;
- Follow-up procedures for corrective action, including debriefing and discussion of possible resolutions;
- Corrective action guidelines to facilitate completion of the reported assessment;
- Appropriate management signature approval of the reviewed assessment report.

3.3.2 Personnel Qualifications for Assessment

The principal Battelle assessor shall be the Quality Assurance Manager, who will have an extensive quality assurance laboratory and field inspection background, and technical and management experience, and who will be directly familiar with the program assessment requirements. Should the need arise, the Quality Assurance Manager will designate an individual to perform scheduled assessments, based upon that person's technical skill and knowledge of QMP compliance requirements and test/QA plan specifications. Battelle personnel conducting assessments shall have the responsibility and authority to:

- Identify and document problems affecting the quality of verification results;
- Propose recommendations for resolving these problems;
- Independently confirm implementation and effectiveness of solutions.

3.3.3 Stop Work

Assessor responsibility and authority to stop work during the program operations for safety and quality considerations is delegated by EPA to Battelle, who must ensure compliance with all onsite Federal, state, and local safety policies during the performance of verification testing.

Should it be determined during an assessment that adverse health effects could result, or that test objectives of acceptable quality cannot be achieved during performance of verification testing, the Quality Assurance Manager is responsible for immediately notifying the Program Manager of the need to consider a stop work order. The Program Manager shall then direct the program staff accordingly.

Should any program staff suspect compromise to personal health or test objectives during the conduct of verification testing, that staff member shall immediately contact the Verification Testing Leader, who shall through vested authority from the Program Manager, issue the stop work order and subsequently notify the EPA TOPO.

The EPA also has the authority to notify the EPA TOPO to facilitate a stop work order if work of inadequate quality is discovered.

Documentation is required of any stop work order and the corrective action implemented and shall be maintained as part of the Battelle quality records, with a copy provided to the EPA.

3.3.4 Internal Assessment Reporting

Authority to effectively report internal technical system audits, performance evaluation audits, and audits of data quality is assigned to the Quality Assurance Manager or designee. Assessment reports will:

- Identify and document problems that affect quality and the achievement of objectives required by the QMP, test/QA plan, and any associated SOPs;
- Identify and cite noteworthy practices that may be shared with others to improve the

quality of their operations and products;
- Propose recommendations (if requested) for resolving problems that affect quality,
- Independently confirm implementation and effectiveness of solutions;
- Provide documented assurance (if requested) to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

3.3.5 Response

Responses to TSA adverse findings shall be addressed within 10 working days after the TSA is completed. However, it is expected that findings that have a direct impact on the conduct of a verification test will be corrected immediately following notification of the finding.

- Responses to each adverse finding shall be documented in the assessment report (QMP Section 3.3.4). Ideally, assessment reports will provide space after each adverse finding for a response to be recorded. The response will indicate the corrective action taken or planned to address the adverse finding. The response shall be signed and dated by the staff responsible for implementing the corrective action.

- Any corrective action that cannot be immediately implemented shall be verified following completion by the Quality Assurance Manager or designee. Once all corrective actions associated with an assessment report have been taken, the Quality Assurance Manager or designee will initial the corrective action in the assessment report thus documenting verification of the corrective action. Any impact that an adverse finding had on the quality of verification test data will be addressed in the verification test report.

- The TSA assessment report, with responses to adverse findings recorded within, will be sent to EPA within 10 working days after the Quality Assurance Manager has verified all corrective actions.

3.4 DATA VALIDATION

Validation is based on the performance measures for the test specified during the design process. The usability of a verification report and statement is determined relative to how well it determines the performance of the tested technology under the conditions of testing. Any limitations on the data and recommendations for limitations on data usability are documented in the data audit report and the ETV verification report.

3.5 REPORT REVIEW

Review and approval procedures for verification reports and statements are given in Table 2-2. Verification reports are peer-reviewed by external reviewers and verification statements are signed by an EPA laboratory or center director.

3.6 QUALITY IMPROVEMENT

3.6.1 Policy

A continuous quality improvement process is considered essential for Battelle staff to develop a more responsive quality system in all aspects of technical and management activities.

3.6.2 Annual QMP Review

An annual review of the QMP for the program shall be conducted by the Quality Assurance Manager and technical and management staff in order to incorporate improvements to the quality system process.

Any revisions to the QMP will be compiled by the Quality Assurance Manager for review, approval, and distribution. The QMP review will be documented by the Quality Assurance Manager and Program Manager by signing and dating the revised QMP routed for review and approval.

3.6.3 Problem Identification and Resolution

Detecting and correcting quality system problems is a result of qualified program technical and management staff implementing not only this QMP, but also the test/QA plans and other procedures. All staff are encouraged to identify problems and offer solutions to problems in the following quality areas:

- Adequacy of the quality system, as defined in the QMP;
- Consistency of the quality system;
- Implementation of the quality system to specific verification tests;
- Correction of quality system procedures;
- Completeness of documented information;
- Quality of data;
- Quality of planning documents, such as the test/QA plans;
- Implementation of the work process.

Cause and effect relationships of significant problems shall be documented by the Quality Assurance Manager. When problems are reported to the Quality Assurance Manager, attempts to determine the root cause based on cause and effect during performance of planned and documented procedures will be made through intensified observations of testing activities and audits of test data.

Collaboration with trained technical/management staff associated with or performing the activity can provide insight and determine whether any of the following is required:

- A test/QA plan change;
- A management system change;
- A quality system change within the program.

Assessment reports can also serve as tools to determine cause and effect relations of significant problems that might require testing protocol, management system, or quality system changes. Continual monitoring and evaluation by the EPA, for example, may indicate trends or common and recurring problems for an entire technology evaluation. In this case, the situation is immediately communicated to the EPA TOPO, who then provides information and any corrective actions.

Root cause determination is immediately reported by Battelle to the EPA prior to any planned implementation of preventative measure. Once the root cause determination is verified, appropriate actions can be planned, documented, and implemented by the program staff.

3.6.4 Ongoing Quality Improvement

Quality improvement action is ongoing in the Battelle quality system, where quality issue action items can be reviewed by all levels of line management at periodic continuous improvement meetings. Quality processes are continually monitored and both short-term and long-term quality issues are identified through customer feedback and client involvement, peer review and internal lessons learned, and monthly program reviews.

Appendix I

Names, Addresses, and Phone Numbers of Key Battelle Program Staff

Key Battelle Program Staff

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Appendix II

Example ETV Verification Statement

THE ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM

U.S. Environmental Protection Agency

Battelle
The Business of Innovation

ETV Joint Verification Statement

TECHNOLOGY TYPE:	**ION MOBILITY SPECTROMETER**		
APPLICATION:	**DETECTION OF CHEMICAL WARFARE AGENTS AND TOXIC INDUSTRIAL CHEMICALS**		
TECHNOLOGY NAME:	**RAID-M**		
COMPANY:	**Bruker Daltonics Inc.**		
ADDRESS:	**40 Manning Road** **Manning Park** **Billerica, MA 01821**	**PHONE:** **FAX:**	**978/663-3660** **978/667-5993**
WEB SITE:	**www.bdal.com**		
E-MAIL:	**ms-sales@bdal.com**		

The U.S. Environmental Protection Agency (EPA) supports the Environmental Technology Verification (ETV) Program to facilitate the deployment of innovative or improved environmental technologies through performance verification and dissemination of information. The goal of the ETV Program is to further environmental protection by accelerating the acceptance and use of improved and cost-effective technologies. ETV seeks to achieve this goal by providing high-quality, peer-reviewed data on technology performance to those involved in the design, distribution, financing, permitting, purchase, and use of environmental technologies. Information and ETV documents are available at www.epa.gov/etv.

ETV works in partnership with recognized standards and testing organizations, with stakeholder groups (consisting of buyers, vendor organizations, and permitters), and with individual technology developers. The program evaluates the performance of innovative technologies by developing test plans that are responsive to the needs of stakeholders, conducting field or laboratory tests (as appropriate), collecting and analyzing data, and preparing peer-reviewed reports. All evaluations are conducted in accordance with rigorous quality assurance (QA) protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

Subsequent to the terrorist attacks of September 11, 2001, this ETV approach has been applied to verify the performance of homeland security technologies. Monitoring and detection technologies for the protection of public buildings and other public spaces fall within the Safe Buildings Monitoring and Detection Technologies Verification Program, which is funded by EPA and conducted by Battelle. In this program, Battelle recently evaluated the performance of the Bruker Daltonics Inc. RAID-M portable ion mobility spectrometer (IMS). This verification statement, the full report on which it is based, and the test/QA plan for this verification are available through a link on the ETV Web site (www.epa.gov/etv/centers/center11.html).

VERIFICATION TEST DESCRIPTION

The objective of this verification test of the RAID-M, a commercially available, portable IMS, was to evaluate its ability to detect toxic chemicals and chemical agents in indoor air. This verification focused on the scenario of a portable IMS used by first responders to identify contaminants and guide emergency response activities after chemical contamination of a building. The following performance characteristics of the RAID-M were evaluated: response time, recovery time, accuracy, response threshold, repeatability, temperature and humidity effects, interference effects, cold-/hot-start behavior, battery life, and operational characteristics. Repeatability was assessed for RAID-M responses, response times, and recovery times.

This verification test took place between August 6 and December 18, 2003. Two units of the RAID-M IMS were tested simultaneously in most parts of this verification; in some cases, failure of a RAID-M required that testing continue with just one instrument. Response time, recovery time, accuracy, and repeatability were evaluated by challenging the RAID-Ms with known vapor concentrations of target toxic industrial chemicals (TICs) and chemical warfare (CW) agents. RAID-M performance at low target analyte concentrations was evaluated to assess the response threshold. Similar tests conducted over a range of temperatures and relative humidities (RHs) were used to establish the effects of these factors on detection capabilities. The effects of potential interferences in an emergency situation were assessed by sampling selected interferences both with and without the target TICs and CW agents present. The RAID-Ms were tested with a single TIC after a cold start (i.e., without the usual warm-up period) from room temperature, from cold storage conditions (5°C), and from hot storage (40°C) to evaluate the delay time before readings could be obtained and the response speed and accuracy of the RAID-Ms once readings were obtained. Battery life was determined as the time until RAID-M performance degraded as battery power was exhausted, in continuous operation. Operational factors such as ease of use, data output, and cost were assessed by observations of the test personnel and through inquiries to the vendor.

Testing was limited to detecting chemicals in the vapor phase because that mode of application is most relevant to use by first responders. Testing was conducted in two phases: detection of TICs (conducted in a non-surety laboratory at Battelle) and detection of CW agents (conducted in a certified surety laboratory at Battelle's Hazardous Materials Research Center). The TICs used in testing were cyanogen chloride (ClCN; North Atlantic Treaty Organization [NATO] military designation CK), hydrogen cyanide (HCN; designated AC), phosgene ($COCl_2$; designated CG), chlorine ($C1_2$; no military designation), and arsine (AsH_3; designated SA). The CW agents were sarin (GB) and sulfur mustard (HD). The RAID-Ms were not programmed to respond to SA, so testing with that TIC was minimal.

For relevance to use by first responders, most test procedures were conducted with challenge concentrations of the TIC or CW agent that were at or near immediately dangerous to life and health (IDLH) or similar levels. Table 1 summarizes the challenge concentrations used in testing. Response thresholds were tested by repeatedly stepping down in concentration, starting from IDLH levels.

QA oversight of verification testing was provided by Battelle and EPA. Battelle QA staff conducted a technical systems audit (TSA), a performance evaluation audit, and a data quality audit of all the test data. An independent TSA was also conducted by EPA.

Table 1. Target TIC and CW Agent Challenge Concentrations

Chemical	Concentrations	Type of Level
Hydrogen cyanide (AC)	50 ppm (50 mg/m^3) and 5 ppm (5 mg/m^3)	1 and 0.1 x IDLH[a]
Cyanogen chloride (CK)	20 ppm (50 mg/m^3) and 2 ppm (5 mg/m^3)	1 and 0.1 x IDLH
Phosgene (CG)	2 ppm (8 mg/m^3) and 0.2 ppm (0.8 mg/m^3)	1 and 0.1 x IDLH
Chlorine (Cl_2)	10 ppm (30 mg/m^3) and 1 ppm (3 mg/m^3)	1 and 0.1 x IDLH
Arsine (SA)	3 ppm (10 mg/m^3)	1 x IDLH
Sarin (GB)	0.014 ppm (0.080 mg/m^3)	0.4 x IDLH
Sulfur mustard (HD)	0.063 ppm (0.42 mg/m^3)	0.7 x AEGL-2[b]

(a) IDLH = Immediately Dangerous to Life and Health; IDLH value for CK estimated from value for AC.

(b) AEGL = Acute Exposure Guideline Level; AEGL-2 levels are those expected to produce a serious hindrance to efforts to escape in the general population. The AEGL-2 value of 0.09 ppm (0.6 mg/m^3) for HD is based on a 10-minute exposure.

TECHNOLOGY DESCRIPTION

The following description of the RAID-M was provided by the vendor and does not represent verified information.

The RAID-M is a chemical detector that uses the principle of IMS to detect, classify, quantify, and continuously monitor concentrations of CW agents and TICs. The identity of substances detected is displayed both by class (e.g., "G," "H," or "T," for G series agents, H series agents, and TICs, respectively) and by specific agent, simulant, or TIC (e.g., "GB," "HD," or "TDI"). All classes can be displayed independently. Relative concentrations are indicated by a bar display with eight increments. In addition to use in the field, the RAID-M is designed to be capable of operating within collective protection facilities.

The RAID-M can be operated while being held in one hand. It has no protruding parts and weighs less than 2.80 kilograms (6.4 pounds), excluding battery. The RAID-M contains a small radioactive sealed source that is completely housed and is such that RAID-M can be stored in bulk. The RAID-M is 400 millimeters (mm) (15.7 inches) long, 115 mm (4.5 inches) wide, and 165 mm (6.5 inches) high. The RAID-M is of a one-tube design, with automatic polarity switching (i.e., both positive and negative ions are automatically monitored, in alternate intervals of 2 to 3 seconds), and is fully microprocessor-controlled. It has a remote display and control option. The display shows agent identity and a relative indication of hazard level. The RAID-M incorporates a built-in audible alarm to indicate agent detection, and visual alarms to warn of a low battery and other faults.

The RAID-M is powered by an integral, primary battery and can accept power input from a variety of sources including vehicles (12- to 24-volt DC nominal) or a 240-volt, 50-Hertz, alternating current power supply. A diagnostic input/output socket provides data output, power input, personal computer connectivity, and built-in test information. The carrying case is designed to protect the RAID-M from exposure to air blasts, thermal radiation, neutron radiation, gamma radiation, and electromagnetic pulse.

Consumables do not need to be changed when the RAID-M detects a challenge, and consumables are designed to have a maximum life of not less than 500 hours. There are no scheduled preventive maintenance tasks. Daily checks are designed to not require dismantling the equipment and to not typically exceed an average of 10 minutes per day.

VERIFICATION OF PERFORMANCE

Table 2 summarizes quantitative results for key RAID-M performance parameters. Additional information and the results of various qualitative evaluations are presented in the subsequent paragraphs.

Table 2. Summary Results for Key Performance Parameters

Performance Parameter	TICs				CW Agents	
	AC	CK	CG	Cl_2	GB	HD
Response time (seconds)	3 to 5	3 to 5	3 to 5	9	10	5 to 8
Recovery time (seconds)	15 to >600	10 to 40	<10	10 to 40	15 to 70	10 to 100
Identification accuracy (%)	nearly 100	nearly 100	nearly 100	nearly 100	97.5	99.4
Response threshold (ppm)	<0.06	<0.6	0.08 to 0.33[a]	0.25 to 0.5[a]	0.0035 to 0.007[a]	0.01 to 0.02[a]
Interferent effects: False negatives[b]				Latex paint fumes, floor cleaner vapors	Latex paint fumes, floor cleaner vapors, air freshener vapors	Latex paint fumes, air freshener vapors, DEAE,[c] gasoline exhaust hydrocarbons

[a] Range shown is based on results from two different RAID-M units.
[b] The indicated interferents reduced or eliminated response to the indicated TIC or CW agent. See text below.
[c] N,N-diethylaminoethanol.

Response Time: Over the ranges of 5 to 35°C and <20 to >80 percent RH, temperature and RH had minimal effect on response time for any TIC or CW agent. Response times for AC were also unaffected by operating the RAID-M from a cold start (i.e., with insufficient warm-up time).

Recovery Time: Recovery times for AC ranged from 15 seconds to over 600 seconds, with the fastest recovery times occurring at low concentrations and high temperatures. In operation from a cold start, the recovery time for AC was lengthened to at least 600 seconds. Recovery times for GB and HD averaged about 50 seconds and about 34 seconds, respectively, at room temperature, with average recovery times reduced by about half at higher temperatures. RH had minimal effect on recovery times.

Accuracy: The RAID-Ms were 100% accurate in identifying the TIC being sampled under almost all test conditions. Accuracy for the CW agents was also high: overall accuracy for GB was 97.5% (excluding data from interferences that suppressed GB response), and for HD was 99.4%, when all test data were included. In addition to correctly identifying GB and HD, the RAID-Ms usually also displayed “HN” (the designation for nitrogen mustard) when sampling either of these agents. For both TICs and CW agents, accuracy was essentially the same when alternating between different challenge concentrations as when alternating between clean air and a challenge concentration. Accuracy below 100% occurred primarily for CK, with the lowest accuracy (~50%) at high humidity and low temperature. The inaccuracy for CK occurred in the form of misidentification of CK as chlorine gas (Cl_2).

Repeatability: Repeatability of response for AC was perfect, as full-scale readings consistently resulted at the

test concentrations. The percent relative standard deviation (%RSD) of recovery times was low for AC primarily because of the long average recovery times for that TIC under many conditions. Response and recovery times were most variable for CK. RAID-M readings and recovery times for Cl_2 were strongly affected by RH, with the most variability at high humidity. For the CW agents, the repeatability of RAID-M response to HD improved as temperature increased, but the repeatability of response time and recovery time for HD lessened. Repeatability of response for GB did not vary substantially with test conditions, and the only effect on repeatability was that recovery times for GB were less repeatable at high humidity.

Temperature and Humidity Effects: Temperature and RH had little effect on RAID-M response to the TICs and CW agents. Higher readings for CK were generally found at lower temperatures, and higher readings for CK and Cl_2 were generally found at lower humidity. Slightly higher readings for both CW agents were also found at lower temperatures.

Interferent Effects: In terms of false negatives, RAID-M response for Cl_2 was sharply reduced by latex paint fumes and floor cleaner vapors; the floor cleaner vapors resulted in zero response for Cl_2. Response to GB was sharply reduced by latex paint fumes, floor cleaner vapors, and air freshener vapors; the latter two interferents resulted in zero response for GB. Response for HD was reduced by about half by latex paint fumes, air freshener vapors, N,N-diethylaminoethanol (DEAE), and gasoline engine exhaust hydrocarbons. However, the interferents also caused the RAID-Ms to display indications of other agents, including the organophosphate nerve agents VX and tabun (GA). False positive responses occurred only with floor cleaner vapors and DEAE. Both of these interferents produced small positive responses in about one-third of the trials; in those cases the RAID-Ms incorrectly identified the interferent as the nerve agent VX.

Cold-/Hot-Start Behavior: Operating the RAID-M with insufficient warmup time reduced the initial responses to AC, regardless of whether the cold start occurred after storage at 5°C, at room temperature, or at 40°C. The response time for AC was not affected by operating from a cold start, but the recovery time was lengthened in such operation. The delay time before a reading could be obtained ranged from 40 seconds to about 3 minutes, except for one unit that showed a delay time of nearly 14 minutes after a 40°C storage and cold start.

Battery Life: The useful operating life for fully charged batteries in two RAID-M units in continuous operation was found to be 6 hours 29 minutes, and 7 hours 52 minutes, respectively.

Operational Characteristics: Several operational characteristics of the RAID-M were noted during testing. In general, the RAID-M was easy to use, gave clear alarms and a readable and informative display, and provided error and diagnostic messages. The RAID-M automatically switched between positive and negative ion detection modes at intervals of a few seconds, allowing detection of a wide variety of chemicals. Among the most important other operational characteristics were

- The use in the RAID-M of two separate software libraries, one for TICs and one for CW agents, necessitating switching between libraries to detect both types of chemicals.
- The need for three types of consumables (carbon backflush filter, drying tube, and ammonia dopant), the first two of which needed to be replaced several times during the nearly five-month test period. RAID-M error messages calling for replacement of consumables are based on metered time of use, not on the actual state of the consumable.
- The need for proper warm-up of the RAID-M before use, to assure that full response is achieved when monitoring starts.
- The failure during testing of two of the three RAID-Ms used in this verification, one due to an electrical fault, and the other to an apparently incorrect error message that required overriding the message by connection to a laptop computer.

original signed by Gabor J. Kovacs 4/2/04
Gabor J. Kovacs Date
Vice President
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Battelle

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E. Timothy Oppelt Date
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Appendix III

ETV Amendment and Deviation Forms

TEST/QA PLAN AMENDMENT

TEST/QA PLAN TITLE AND DATE:

VENDOR/TECHNOLOGY:

AMENDMENT NUMBER: _____

EFFECTIVE DATE: _____

PART TO BE CHANGED/REVISED:

CHANGE/REVISION:

REASON FOR CHANGE:

ORIGINATED BY:

_____
Verification Test Coordinator

_____
Date

APPROVED BY:

_____ _____
Verification Test Leader Battelle Quality Assurance Manager

_____ _____
Date Date

Required Distribution –
All individuals/organizations listed on distribution for the applicable test/QA Plan, including but not limited to:

- Battelle Program Management
- Battelle Testing Staff
- Battelle Quality Assurance Manager
- Verification Test Partners (if any)
- EPA TOPO
- EPA Quality Staff
- Vendors

Distribution must be documented

TEST/QA PLAN DEVIATION REPORT

TEST/QA PLAN TITLE AND DATE:

DEVIATION NUMBER: _____ **DATE OF DEVIATION:** _____

DESCRIPTION OF DEVIATION:

CAUSE OF DEVIATION:

IMPACT OF DEVIATION ON THE TEST:

CORRECTIVE ACTION:

ORIGINATED BY:

_____
Verification Test Coordinator

_____
Date

ACKNOWLEDGED BY:

_____
Verification Testing Leader

_____
Date

_____
Battelle Quality Assurance Manager

_____
Date

Required Distribution –

Battelle Program Management
Battelle Quality Assurance Manager